*** *Submit This Page With Application* ***

FOR OFFICE USE ONLY
Receipt #
ID #
Issue Date
License # DIS CDIS

State of Rhode Island
Board of Pharmacy

Room 205
3 Capitol Hill
Providence, RI 02908-5097

Instructions and Application For

Distributor License and Controlled Substances Registration

Check Box(es):

- ☐ New Application
- ☐ Change of Location (License # _____)
- ☐ Wholesaler
- ☐ Manufacturer
- ☐ Controlled Substances Registration
- ☐ Change in Ownership (License # _____)

Applicant - Print Full Facility Name

Phone: (401) 222-2837 **TTY/TDD: (800) 745-5555** **Fax: (401) 222-2158**

*** *Detach Page - Do Not Submit With Application* ***

GENERAL INFORMATION

Enclosures

The following materials and information should be enclosed within this application packet:

Licensure Requirements

Wholesaler (out of state)

Fee(s) Application - **$125.00**
RI Controlled Substances Registration - **$50.00** (if applicable)
Licensure in state in which located
Federal Drug Enforcement Administration (DEA) Registration (if applicable)

Manufacturer (out of state)

Fee(s) Application - **$125.00**
RI Controlled Substances Registration - **$50.00** (if applicable)
Federal Registration of Establishment
Licensure in state in which located
Federal Drug Enforcement Administration (DEA) Registration (if applicable)

Every wholesale distributor and/or manufacturer, wherever located, who engages in wholesale distribution into, out of, or within this state, must be registered licensed by the Board in accordance with the laws and regulations of this state, before engaging in wholesale distribution of prescription drugs. Where operations are conducted at more than one location by a single wholesale distributor, each such location distributing into the state shall be registered licensed by the Board. Each board of pharmacy in the state(s) in which the applicant holds a registration or license shall submit to the Department in this state a statement confirming the applicant holds a current license in good standing in said state.

A "**Wholesaler"** is a person who buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers. A **"Wholesale Distributor"** is anyone engaged in the wholesale distribution of drugs, including, but not limited to, manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies that conduct wholesale distribution.

"Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug or poisons. ***"Manufacturing"*** means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substances or labeling or relabeling of its container, and the promotion and marketing of such drugs and devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacists, practitioners, or other persons.

Wholesale drug distributors and/or manufacturers that deal in controlled substances shall register with the Department of Health, and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulations.

"Wholesale distribution" means distribution of prescription drugs to person other than a consumer or patient, but does not include:

- intracompany sales;
- the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
- the sale, purchase or trade of a drug of an offer to sell, purchase, or trade a drug by a charitable organization to a non-profit affiliate of the organization to the extent otherwise permitted by law;
- the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control. For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract or otherwise;
- the sale, purchase or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;
- the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.
- the lawful distribution of drug samples by manufacturers' representatives or distributors' representatives.
- the sale, purchase, or trade of blood and blood components intended for transfusion.

Where operations are conducted at more than one location by a single wholesale distributor, each such location distributing into the state shall be licensed by the Board. Each board of pharmacy in the state(s) in which the applicant holds a registration or license shall submit to the Department in this state a statement confirming the applicant holds a current license in good standing in said state.

Web Sites

Board of Pharmacy	**www.healthri.org/hsr/professions/pharmacy.htm**
License Verifications (All license types) 	**http://63.72.31.182/** (Use the above web site to print a verification of licensure prior to receipt of the official license.)

State of Rhode Island Rules and Regulations

Pharmacy Act	**www.rules.state.ri.us/rules/released/pdf/DOH/DOH_2077.pdf**
Disposal of Drugs	**www.rules.state.ri.us/rules/released/pdf/DOH/DOH_165_.pdf**
Distributors of Controlled Substances	**www.rules.state.ri.us/rules/released/pdf/DOH/DOH_164_.pdf**
Electronic Data Transfer	**www.rules.state.ri.us/rules/released/pdf/DOH/DOH_162_.pdf**
Hypodermic Needles/Instruments	**www.rules.state.ri.us/rules/released/pdf/DOH/DOH_163_.pdf**

State of Rhode Island Statutes

Pharmacy Act	**www.rilin.state.ri.us/statutes/title5/5-19-1/INDEX.HTM**
Controlled Substances Act	**www.rilin.state.ri.us/statutes/title21/21-28/INDEX.HTM**
Controlled Substances Therapeutic Research Act	**www.rilin.state.ri.us/statutes/title21/21-28-4/INDEX.HTM**
Drugs & Poisons Generally	**www.rilin.state.ri.us/statutes/title21/21-30/INDEX.HTM**
Food, Drugs & Cosmetics Act	**www.rilin.state.ri.us/statutes/title21/21-31/INDEX.HTM**
Poison Prevention Packaging Act	**www.rilin.state.ri.us/statutes/title23/23-14-1/INDEX.HTM**

Federal Statutes/Forms/Manuals

Code of Federal Regulations	**www.access.gpo.gov/nara/cfr/cfr-table-search.htm**
DEA Registration Form (224, 224A)	**www.deadiversion.usdoj.gov/drugreg/reg_apps/index.html**
DEA Applications and Reports On-line (Form 106, 41 ...)	**www.deadiversion.usdoj.gov/21cfr_reports/index.html**

APPLICATION PROCESS OVERVIEW

The licensure process in the State of Rhode Island is conducted by the Rhode Island Department of Health (HEALTH), Office of Health Professions Regulation, and the Rhode Island Board of Pharmacy (BOARD).

Application Process

This application is to be used for a new license as a drug distributor (out-of-state wholesaler or manufacturer), and to apply for a new license due to a change in ownership or location. A license will be issued to a person, owner, corporation, or other legal entity, hereinafter called the "Licensee". The license shall entitle the owner to operate such facility at the location specified and shall not be transferred. When there is a change in ownership, operation and/or location, the license immediately becomes void and shall be delivered by the licensee to the BOARD. It is the duty of the owner to immediately notify the BOARD of any proposed change of location or ownership, and to file the required application prior to the change. Changes in any information required by this section shall be submitted to the Department within fifteen (15) days of change.

"Change of ownership" means:

a. In the case of a pharmacy, manufacturer or wholesaler which is a partnership which results in a new partner acquiring a controlling interest in the partnership;
b. In the case of a pharmacy, manufacturer or wholesaler which is a sole proprietorship, the transfer of the title and property to another person;
c. In the case of a pharmacy, manufacturer or wholesaler which is a corporation:

    i. A sale, lease exchange, or other disposition of all, or substantially all of the property and assets of the corporation; or
    ii. A merger of the corporation into another corporation; or
    iii. The consolidation of two or more corporations, resulting in the creation of a new corporation; or
    iv. In the case of a pharmacy, manufacturer or wholesaler which is a business corporation, any transfer of corporate stock which results in a new person acquiring a controlling interest in the corporation; or
    v. In the case of a pharmacy, manufacturer or wholesaler which is a nonbusiness corporation, any change in membership which results in a new person acquiring a controlling vote in the corporation.

All items listed on the "checklist" (page 11) must be submitted for an application to be considered complete. All applications are considered valid for six months from the day they are received at HEALTH. If the application process is not completed and a license issued within those six months, a new application and fee must be submitted.

If the applicant has had criminal or disciplinary history in Rhode Island or another state, it may take an additional two or three months for all pertinent documentation to be received, and a decision to be made regarding the issuance of a license. This is an estimate of the amount of time that is required to become licensed. The entire process may take more or less time than estimated.

Licenses will be issued within five working days following the Board's approval of the completed application. Wall permits are mailed approximately two weeks from the date of issuance, and are mailed to the address furnished in the application. It is the applicant's responsibility to notify the BOARD, in writing, if there are changes during the interim, or at any time after the license is issued.

HEALTH will not, for any reason, expedite processing of one applicant at the expense of other applicants. Once completed, the application will be reviewed, and will be contacted by the BOARD if further information is required. Be advised, the applicant may be required to appear for an interview.

NOTE: The license will expire on June 30th ***(regardless of the date issued)***, and a form will be mailed to renew the facility license and Controlled Substances Registration for the period July 1st through June 30th. It is the licensee's responsibility to maintain an active license. If a renewal is not received, the licensee is to contact the BOARD, and follow-up on the status of the renewal. Information on the status of the renewals can be obtained at HEALTH'S web site.

www.healthri.org

Please continue to review the remaining portions of this application packet for instructions and other materials necessary to complete the Board application. If you have any questions about this application process, or would like to check on the status of your BOARD application, please contact the BOARD at (401) 222-2837.

*** *Detach Page - Do Not Submit With Application* ***

INSTRUCTIONS FOR COMPLETING THE BOARD APPLICATION

Read the following instructions and those throughout the application packet carefully before completing the Board application. **Only complete applications with the appropriate fee will be accepted.** Failure to submit all required information and appropriate documentation may result in processing delays. All of the information provided is subject to change.

General Instructions

1. Make a copy of the application and forms before you begin in case you make a mistake.
2. Type the information or print in blue or black ball-point pen. Board staff will not make assumptions about illegible information. Be sure to check the appropriate box(es) on the cover page of the application, and print the licensee's name in the box provided.
3. Provide a response to each section or question; otherwise mark "N/A" for Not Applicable.
4. It is suggested that a copy of the completed application be made before submitting it to the Board.
5. It is the applicant's responsibility to check on the status of the application.

Completing your Board Application

1. Complete the **Board Application** pages (6-10). Respond to all components of the application as instructed. If you attach separate pages in continuation of the Board application, such pages MUST clearly indicate the section for which such information is being reported.
2. Make a check or money order (in U.S. Funds only) for the application fee of **$125.00** payable to **General Treasurer, State of Rhode Island** and staple it to the upper left-hand corner of the cover page of the application.
3. Include, if applicable, an additional **$50.00** for the Rhode Island Controlled Substances Registration.

A Controlled Substances Registration (CSR) is mandatory for all new pharmacies that will dispense controlled substances. The fees are NONREFUNDABLE. A Drug Enforcement Administration (DEA) Registration is also required. Contract the **DEA** at **617-557-2200** for the application. The RI CSR is contingent upon a DEA Registration being issued.

Complete all application materials as instructed and arrange them in order as they appear in the application checklist (see page 11). Do not submit applications without all applicable information, documentation and fee. Mail these components of the application to:

Rhode Island Department of Health
Board of Pharmacy
Room 205, Three Capitol Hill
Providence, RI 02908-5097

Please include the cover page of this package with the application.

State of Rhode Island
Board of Pharmacy

Application for a License to Distribute Drugs and Controlled Substances Registration

Refer to the Application Instructions when completing these forms. Type or block print only. Do not use felt-tip pens.

1. Preferred Mailing Address

Complete this section if mail is to be delivered to an address other than the facility location. If not, write "N/A" and proceed to question #2.

First Line Address (Additional Address Information, if necessary)

Second Line Address (Apartment, etc).

Third Line Address (Number and Street)

City | State | Zip Code

2. Facility Information

Provide the name, address and telephone number(s) for the facility.

Please note:

Facility Name does not necessarily reflect the legal license holder. The license is issued in the name of the owner,

Name of Facility

First Line Address (Additional Address Information, if necessary)

Second Line Address (Suite/Room Number, etc.)

Third Line Address (Number and Street)

City | State | Zip Code

Facility Phone | Extension | Facility Fax

NABP Number | Facility E-Mail Address

3. Manager

Provide the name of the individual who is responsible for the day-to-day operations of the facility.

A change in Manager requires written notification to the Board.

Position (i.e. Owner, Manager, etc.) | Title (i.e., Mr., Mrs., Ms., etc.)

First Name

Middle Name

Surname, (Last Name)

Suffix (i.e., Jr., Sr., II, III) | License Number (if applicable)

4. Licensee Information (Type of Ownership)

Please select one

- ☐ Sole Proprietorship (Go to question #4)
- ☐ Corporation (Go to question #6)
- ☐ Partnership (Go to question #5)
- ☐ Limited Liability Company (Go to question #6)
- ☐ Limited Partnership (Go to question #5)
- ☐ Governmental Entity (Go to question #6)
- ☐ Other (Describe): (Go to question #5)

5. Sole Proprietorship (Individual Ownership)

Provide the name, address and telephone number(s) of owner here (If sole proprietorship).

NOTE: If the OWNER is NOT a single person, skip to Question #6

SOLE OWNER | Title (i.e., Mr., Mrs., Ms., etc.)

Position (i.e. Owner, Manager, etc.)

First Name

Middle Name

Surname, (Last Name)

Suffix (i.e., Jr., Sr., II, III)

5. Sole Proprietorship (Continued)

First Line Address (Additional Address Information, if necessary)

Second Line Address (Apartment, etc).

Third Line Address (Number and Street)

City | State | Zip Code

Country, If NOT U.S. | Postal Code, If NOT U.S.

Home Phone | Home Fax

Email Address (Format for email address is username@domain (e.g. applicant@isp.com))

6. Partnership, Corporation, or Governmental Entity Information

Provide the name, address and telephone number(s) of the Partnership, Corporation, or Governmental Entity.

NOTE: Skip this question if you completed owner information in question #4.

Name of Partnership, Corporation, or Governmental Entity

D.B.A. (Doing Business As)

First Line Address (Additional Address Information, if necessary)

Second Line Address (P.O. Box/Suite/Room Number, etc.)

Third Line Address (Number and Street)

City | State | Zip Code

Country, If NOT U.S. | Postal Code, If NOT U.S.

Partnership , Corporation, or Governmental Entity Phone | Extension | Partnership, Corporation or Governmental Entity Fax

Email Address (Format for email address is username@domain (e.g. applicant@isp.com))

F.E.I.N. (Federal Employee Identification Number)

7. Parent Organization, Group, Affiliation

Complete this section if there is a parent organization, group affiliation or other entity that is on the top of the facility's chain of control.

Name of Parent Organization or Group Affiliation

D.B.A. (Doing Business As)

First Line Address (Additional Address Information, if necessary)

Second Line Address (P.O. Box/Suite/Room Number, etc.)

Third Line Address (Number and Street)

City | State | Zip Code

Country, If NOT U.S. | Postal Code, If NOT U.S.

Phone Number | Extension | Fax Number

Email Address (Format for email address is username@domain (e.g. applicant@isp.com))

F.E.I.N. (Federal Employee Identification Number)

Print Facility Name Here>

8. Partnership, Corporation or Other Ownership

List name, title and residence of each partner, corporate officers, director, and other person of similar status or function.

Attach separate sheet if necessary.

Position (i.e. President, Vice-President, etc.)

Title (i.e., Mr., Mrs., Ms., etc.)

First Name

Middle Name

Surname, (Last Name)

Suffix (i.e., Jr., Sr., II, III)

First Line Address (Additional Address Information, if necessary)

Second Line Address (Apartment, etc).

Third Line Address (Number and Street)

City

State

Zip Code

Position (i.e. President, Vice-President, etc.)

Title (i.e., Mr., Mrs., Ms., etc.)

First Name

Middle Name

Surname, (Last Name)

Practitioner With Prescribing Privilege? ☐ Yes ☐ No

Suffix (i.e., Jr., Sr., II, III)

Financial Interest (%)

First Line Address (Additional Address Information, if necessary)

Second Line Address (Apartment, etc).

Third Line Address (Number and Street)

City

State

Zip Code

Position (i.e. President, Vice-President, etc.)

Title (i.e., Mr., Mrs., Ms., etc.)

First Name

Middle Name

Surname, (Last Name)

Practitioner With Prescribing Privilege? ☐ Yes ☐ No

Suffix (i.e., Jr., Sr., II, III)

Financial Interest (%)

First Line Address (Additional Address Information, if necessary)

Second Line Address (Apartment, etc).

Third Line Address (Number and Street)

City

State

Zip Code

9. Rhode Island Controlled Substances Registration (CSR)

Complete this area for applying for a registration to dispense and possess controlled substances in the State of Rhode Island.

A CSR is not required if there are no controlled substances stored on the premises, or shipped into the state.

The CSR is renewed at the same time as the facility license.

Do you wish to apply for a Rhode Island Controlled Substances Registration.

☐ Yes ☐ No If ***"yes"***, the additional fee must be included in payment.

Drug Schedules - Check all applicable.

Attach Protocol

☐ Schedule I ☐ Schedule II ☐ Schedule III ☐ Schedule IV ☐ Schedule V

Drug Enforcement Administration (DEA) Registration

Provide DEA number if one has been issued, or check "pending" if an application is being made for the DEA Registration.

☐☐☐☐☐☐☐☐☐ DEA Number

☐ Pending

A copy of the DEA Registration must be provided to the BOARD within 60 days of its issuance.

Carefully read this section.

IMPORTANT INFORMATION

Licensed drug wholesalers ship or possess controlled substances in the State of Rhode Island without a valid drug wholesaler license, Rhode Island Controlled Substances Registration (CSR), and a federal Drug Enforcement Administration (DEA) Registration. "Controlled Substances" for purposes of this application, means a prescription drug in Schedules II through V, pursuant to the Rhode Island Uniform Controlled Substances Act, and 21 CFR 1300 of the Federal Code of Regulations. Schedule I drugs are used by researchers, and require the submission of a protocol.

Without a Rhode Island CSR, and federal DEA Registration, drug wholesalers may ship or possess non-controlled prescription medications under its wholesaler license. No CSR will be granted to a wholesale applicant whose application is "pending" in this state. If any of the questions in Section 17 were answered "yes", a typed explanation must be provided on a separate sheet of paper.

All applicants must make application to the U.S. Drug Enforcement Administration for a federal registration. Federal regulations require that applicants comply with individual state requirements before they are issued a DEA Registration.

Registration Unit
US Drug Enforcement Administration
JFK Federal Building
15 New Sudbury Street
Boston MA 02203-0131
(617) 557-2200

Issuance of a Rhode Island Controlled Substances Registration is contingent upon registration from the U.S. Drug Enforcement Administration. If denied a "DEA Registration", the Rhode Island Controlled Substances Registration becomes "VOID".

A copy of the DEA Registration must be provided to the BOARD within 60 days of its issuance.

10. Affidavit of Applicant

Complete this section and sign in the presence of a notary public. Make sure that you and the notary public have completed all components accurately and completely.

I, _____, being first duly sworn, depose and say that I am the person referred to in the foregoing application and supporting documents.

I hereby authorize all hospital(s), institution(s) or organizations(s), my references, personal physicians, employers (past and present) and all governmental agencies and instrumentality's (local, state, federal or foreign) to release to the Rhode Island Board of Pharmacy any information which is material to my application for licensure.

I have read carefully the questions in the foregoing application and have answered them completely, without reservations of any kind, and I declare under penalty of perjury that my answers and all statements made by me herein are true and correct. Should I furnish any false information in this application, I hereby agree that such act shall constitute cause for denial, suspension or revocation of my license to practice medicine/ surgery in the State of Rhode Island.

I understand that my records are protected under the Federal and State Regulations governing Mental Health Patient Records and cannot be disclosed without my written consent unless otherwise provided in the regulations. I understand that my records are protected under the Federal and State Regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2, and cannot be disclosed without my written consent unless otherwise provided in the regulations.

I understand that this is a continuing application and that I have an affirmative duty to inform the Rhode Island Board of Pharmacy of any change in the answers to these questions after this application and this affidavit is signed.

_____ _____

Signature of Applicant | Date of Signature (MM/DD/YY)

The foregoing instrument was acknowledged before me this _____ day of _____, 20_____, by _____, who is personally known to me or has produced _____ as documentation and did/did not take an oath.

_____ _____

Name of Notary (Print, Type or Stamp) | Signature of Notary

Notary Seal

_____ _____

Notary No/Commission No. | Commission Expiration Date (MM/DD/YY)

*** *Detach Page - Do Not Submit With Application* ***

APPLICATION CHECKLIST

Please review the following checklist to ensure that all the components of the application process has been satisfied. Some items may not apply.

Board Application

- ☐ I have read and understand the "Instructions for Completing the Application."
- ☐ I have completed the Rhode Island Board application as instructed on Page 5.
- ☐ I have completed Section 10, **"Affidavit of Applicant"**, and had the form notarized by a notary public.
- ☐ I have a **check** or **money order** (preferred), made payable (in U.S. funds only) to the ***"RI General Treasurer"*** in the amount of **$125.00**, and have attached it to the upper left-hand corner of the cover page of the application.
- ☐ I completed Section 9, **"Rhode Island Controlled Substances Registration (CSR)"**, and have added an additional **$50.00** to the fee that is required.
- ☐ I have arranged my Board Application materials in the following order.

    1. Fee(s) [attached as instructed].
    2. Board Application (including cover page of application), and pages 6-10).
    3. Supporting documentation as required. [**Note:** Pages containing additional information in continuation of the Board application MUST indicate the section for which the information is being reported.]
    4. Copy of license issued by state in which located.
    5. Copy of DEA registration (if applicable)

- ☐ I have mailed the above application materials directly to the Board of Pharmacy, Department of Health.